IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Juan Mantelle et al.
Title:	TRANSDERMAL COMPOSITIONS CONTAINING LOW MOLECULAR WEIGHT DRUGS WHICH ARE LIQUID AT ROOM TEMPERATURES
Application No.:	09/986,945
Filing Date:	11/13/2001
Examiner:	Nabila G. Ebrahim
Art Unit:	1618
Confirmation No.:	6420

REPLY BRIEF

Mail Stop Appeal Brief - Patents
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Sir:

The following is Appellant's Reply Brief under 37 C.F.R. § 41.41, which is being filed in response to the Examiner's Answer mailed on May 5, 2009.

A Request for Oral Hearing is submitted herewith, along with payment of the required fee.

The Commissioner is hereby authorized to charge any deficiency in fees (or credit any overpayment) to Deposit Account no. 19-0741.

I. Arguments

Appellant responds to the new issues raised in the Examiner's Answer below.

A. The Claims are Definite As Required By §112, Second Paragraph

On page 3, the Examiner's Answer alleges that claim 1 is indefinite because the phrase "below processing temperature" is unclear, and that claims 1 and 5 are indefinite for reciting the phrase "equal to or greater than the normal boiling points of the at least one low molecular weight drug." On page 8, the Examiner's Answer states that the phrases at issue do not inform the public "of the boundaries of what constitutes infringement" because they recite "properties of materials that are not recited in the claims such as the active agent and/or the adhesive polymers," and refer to "unknown values that are related to properties of an unknown material."

In response, Appellant emphasizes that the phrases at issue clearly set boundaries around the invention, and will be readily understood by the skilled artisan setting out to practice, or avoid infringement of, the claimed invention. Thus, temperatures that read on the "below processing temperatures" language will be immediately known when the processing temperatures (*e.g.*, the temperatures used when making the transdermal drug delivery system, as outlined at pages 10-11 of the specification as filed) are selected, and temperatures that are "equal to or greater than the normal boiling points of the at least one low molecular weight drug" will immediately be known (or readily ascertainable) when the at least one low molecular weight drug is selected. The claims do not have to recite numerical values for these parameters in order to satisfy §112, when these values will immediately be known (or readily ascertainable) when the claimed invention is being practiced or avoided.

B. Miranda Does Not Anticipate The Claimed Transdermal System

At page 9, the Examiner's Answer alleges that Miranda discloses using the same polyacrylates to deliver the same drug transdermally, and so must necessarily anticipate the claims on appeal, because "a compound and its properties are not separable."

In response, Appellant again emphasizes that Miranda simply does not teach or suggest the use of a high shear resistant acrylic-based polymer as claimed. Thus, contrary to the statement in the Examiner's Answer and previous Office Actions, Miranda does not, in

fact, disclose the use of "the same" acrylic polymers as recited in the claims on appeal. Appellants have submitted evidence (included in the Evidence Appendix) demonstrating that the specific acrylic based polymers listed in Miranda, such as Duro-Tak 80-1194, Duro-Tak 80-1196, and Duro-Tak 80-1197, do not possess high shear resistant properties recited in the claims. Thus, the anticipation rejection based on Miranda is unfounded.

On page 10, the Examiner's Answer notes that the parent patent (U.S. Patent No. 6,316,022) teaches that Duro-Tak 80-1194, Duro-Tak 80-1196, and Duro-Tak 80-1197 can be used in the described invention. (Appellant notes that the same disclosure appears in the application on appeal). However, the Board must appreciate that the specification may describe embodiments that are outside the scope of the claims. Thus, for example, while the specification teaches that "a high shear resistant polymer" may have a shear resistance of $\geq$ 50 hours at ***4 psi***, the instant claims recite polymers with a greater shear resistance, e.g., $\geq$ 50 hours at ***8 psi***. The fact that the prior art mentions polymers that may be used in ***unclaimed*** embodiments described in the specification in no way means that Appellant is "contradicting his own disclosure" as alleged at page 10, let alone that the prior art anticipates the claimed invention.

C. Pfister Does Not Anticipate The Claimed Transdermal System

On page 11, the Examiner's Answer alleges that the carbomers used by Pfister are acrylic-based polymers that possess a shear resistance as recited in the pending claims, citing Table C2 of Pfister.

Appellant responds that Table C2 of Pfister reports on the shear properties of Pfister's composition as a whole, not on the shear properties of the carbomers *per se*. Thus, Table C2 does not support the assumption that Pfister's carbomers read on the recited high shear resistant acrylic-based polymers.

On page 12, the Examiner's Answer asserts that because the carbomers of Pfister may have a molecular weight that overlaps with the molecular weight recited in the instant claims, "it is the position of the Examiner that . . . the shear resistance is expected to overlap as well."

In response, Appellant emphasizes that the Examiner cited no evidence in support of the assumption that there is ***necessarily*** a direct correlation between molecular weight and

shear resistance, as would be required to support an anticipation rejection on the basis that Pfister's carbomers inherently possess the claimed shear resistance properties based on their molecular weights.

With regard to claim 1, Appellant responds further that claim 1 recites that the transdermal drug delivery system comprises a "high shear resistant acrylic-based ***pressure-sensitive adhesive polymer***," whereas Pfister's carbomers are not pressure-sensitive adhesives. Thus, Pfister simply cannot anticipate claim 1.

D. The Claimed Transdermal System Is Not Obvious

On page 12, the Examiner's Answer alleges that because Pfister anticipates the instant claims, it "consequently makes obvious all the claims combined with Lee and Hortsman."

Appellant states in response that because Pfister does not anticipate the invention recited in the independent claims, as shown above, and because the cited secondary references (Lee and Hortsman) do not remedy the deficiencies of Pfister in that regard, the combination of Pfister, Lee and Horstman does not render obviousness the subject matter of the claims on appeal.

CONCLUSION

For the reasons set forth above and in the Appeal Brief, the pending rejections are improper and should be reversed.

Respectfully submitted,

Date July 2, 2009 By _____

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